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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

**Office Action Summary**

Application No.

09/431,008

Applicant(s)

BURBANK ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 12-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-21 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 25 November 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Response to Amendment***

The drawing and specification objections have been withdrawn in view of the proposed drawing and amendment filed 11/25/02.

The claim rejections under 35 USC § 112, 2<sup>nd</sup> paragraph have been withdrawn in of the amendment filed 11/25/02.

The double patenting rejection is maintained since applicant has failed to submit a terminal disclaimer. None have been received, although applicant has remarked that a TD has been submitted. Upon receipt and verification of the TD, the double patenting rejection will be withdrawn.

### ***Specification***

The disclosure is objected to because of the following informalities: A brief description of Fig. 3B is missing.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no support for the valve lock to shift and lock the valve assembly "prior to the seating of the access tube in the bore of the valve assembly".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 3763

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See specification objection. For the purpose of art rejection, inasmuch as applicants have shown their device to work with a valve lock, so has the Examiner.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2,6 rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty (U.S. Patent No. 5,702,363).

See figs. 1-2 of Flaherty, specifically 2. Flaherty discloses an implantable port comprising a base ( 2, 2",2'") having a passage for receiving an access tube (240), a valve assembly (246) being a duckbill valve and a valve lock having a latch which shifts position to lock the valve assembly open. The valve lock is considered to be element 220' and 233, 248. The valve lock is considered to latch onto to the duckbill valve by shifting position to maintain the duckbill valve open when the access tube is inserted such that the duckbill valve is opened in response to the movement of the access tube/needle and also the latch. The reference is capable of performing the functional limitations as claimed.

Claims 1-3,6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ensminger et al. (U.S. Patent No. 5,476,451).

Ensminger et al. disclose an implantable port having a base having a passage See figs. 22-25 cols 14. Ensminger et al. show a valve assembly 296, having a bore (297) which receives an access tube (304) and is capable of being open in response to movement of the access tube (304). Ensminger et al. further show a valve lock (288) having a latch which comprises at least one space-filling element which is displaced from the passage into a receptacle (302) . See fig. 23 and 25. With respect to the functional language, the device of Ensminger et al. is capable of performing the function. Although Ensminger et al. discloses the levers 290 and 290' to be manually moved for the access tube (304) to be inserted, it is the Examiner's position that with

Art Unit: 3763

the beveled end of the tube (304), would be capable of insertion into the bore such that the space filling element is shifted into the receptacle and remains there so long as the access tube stays in the bore.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flaherty ( U.S. Patent No. 5,702,363) in view of White (U.S. Patent No. 4,393,882).

Flaherty discloses the invention as substantially claimed. See above. Flaherty further shows a tapered bore at the proximal end of the valve lock (220', 233,248). Fig. 1 shows a better view of the valve lock when there is no access tube. The tapered is considered to be the proximal end to the points of contact with the access tube at 233. Flaherty teaches the seal element (233) for engaging the access tube to prevent leakage. See col. 7, 13-21. In the event that applicant is not convinced that Flaherty anticipates the tapered bore, then it would have been obvious to modify the bore of Flaherty as taught by White ( White teaches a tube in a tapered bore of a fluid device for sealing such that there's no leakage. See fig. 2 and 3. ) in order to provide a good seal to prevent leakage.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims, 112-113, and 123-124 of U.S. Patent No. 6,007,516. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. The claims of the application claim an implantable port comprising a base having a passage, a valve assembly in the base having a bore wherein the valve assembly opens in response to insertion of the access tube, and a valve lock having a latch which shifts to lock the valve assembly open. The patent claims recite an implantable port comprising a base having a passage, a valve assembly in the base having a bore wherein the valve assembly opens in response to insertion of the access tube, and a pair of balls disposed between the passage and the bore which are spring-biased to close against and lock the access tube. Since a broad interpretation of the

Art Unit: 3763

latch includes the pair of balls, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the 6,007,516 patent.

***Allowable Subject Matter***

Claims 12-20 are allowable over the prior art.

***Response to Arguments***

Applicant's arguments filed 11/25/02 have been fully considered but they are not persuasive.

The Examiner is not convinced the amendment overcomes the rejection in view of the new matter rejection. If applicant can provide support that applicant's invention is capable of shifting the latch ( pair of balls) without entry of the needle into the bore then the Examiner may reconsider the art rejection. As best understood by the Examiner the rejection still holds the prior art rejection readable of the claims. Flaherty 's latch is in the broadest sense the elements which latches by constriction fit of the elements.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday - alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

BRIAN L. CASLER  
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Art Unit 3763